

Applicant : Gary W. Cleary et al.
Appln. No. : 10/625,327
Page -5-

In the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (currently amended) A transdermal, ~~[[dermal,]]~~ transmucosal~~[[, -mucosal]]~~ active delivery system comprising:

an ultra thin polymeric film member having a thickness of less than 0.002 inches;

a layer of adhesive coating at least a portion of a first side of said ultra thin film, whereby said layer of ultra thin film can be adhered to a dermal or mucosal layer; and

~~[[an]]~~ a transdermally-effective active ingredient secured to said first side of said ultra thin film.

2. (currently amended) The device of claim 1 in which said transdermally-effective active ingredient comprises a pharmacologically active ingredient that is incorporated into said adhesive layer.

3. (original) The device of claim 2 in which said adhesive layer entirely covers said first side of said ultra thin film.

4. (currently amended) The delivery system of claim 1 in which said transdermally-effective active ingredient is incorporated into a gel layer which is adhered to said first side of said ultra thin film.

5. (currently amended) The device of claim 4 in which said adhesive layer entirely covers said first side of said ultra thin film and serves to adhere said transdermally-effective active ingredient containing gel layer to said first side of said ultra thin film.

Applicant : Gary W. Cleary et al.
Appln. No. : 10/625,327
Page -6-

6. (currently amended) The device of claim 1 in which said transdermally-effective active ingredient is contained in an island member whose dimension are less extensive in scope then the dimensions of said ultra thin film;

said island member comprising a backing member to which said transdermally-effective active ingredient is secured;

said backing member being adhered to said ultra thin film layer by said first adhesive layer.

7. (currently amended) The device of claim 6 in which said transdermally-effective active ingredient is incorporated into a layer of adhesive which is applied to said island backing member.

8. (currently amended) The device of claim 6 in which said transdermally-effective active ingredient is incorporated into a gel layer adhered to said island backing member.

9. (original) The device of claim 6 in which said first adhesive layer entirely covers said first side of said ultra thin film.

10. (currently amended) The device of claim 6 in which said transdermally-effective active ingredient is contained in a reservoir adhered to said island backing member.

11. (currently amended) The device of claim 1, wherein said ultra thin film has a thickness of between about ~~0.003~~ 0.0003 and about 0.0015 inches.

12. (currently amended) A transdermal-dermal, transmucosal-mucosal delivery system comprising:

a handle having a first adhesive coated on a first side thereof;
an ultra thin polymeric film with a thickness under 0.002 inches and having a first and a second side;

a second adhesive ~~coated~~ layer on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;

[[an]] a transdermally-effective pharmacologically active ingredient secured to said first side of said ultra thin film;

a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle;

wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa.

13. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein said first side of said handle is entirely coated with the first adhesive.

14. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 13, wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

15. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 13, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

16. (currently amended) The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein the ~~second~~ ultra thin film has a thickness [[is]] between about 0.0003 and about 0.0015 inches.

Applicant : Gary W. Cleary et al.
Appln. No. : 10/625,327
Page -8-

17. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein the first side of the second film is entirely coated with the second adhesive.

18. (original) The delivery system of claim 12 in which said release liner comprises two separate portions, a first portion covering a portion of said first side of said ultra thin film and a second portion covering the remainder of said first side of said ultra thin film;

each of said release liner portions including at least a tab portion extending beyond the perimeter of said handle, whereby a user can grasp one portion of said release liner by its said tab using one set of digits and can grasp the remainder of the delivery system using another set of digits, and then peel said first portion of said release liner away from said delivery system, and can thereafter grasp the exposed portion of the delivery system with one set of digits and grasp said tab of said second portion of said release liner with another set of digits and peel said second portion of said release liner away from the remainder of said delivery system.

19. (original) The delivery system of claim 18 in which said first portion of said release liner covers at least that portion of said handle which extends beyond said ultra thin film, such that when said first portion of said release liner is peeled away, the extending portion of said handle can be grasped, without also grasping a portion of said ultra thin film.

20. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein the first and second adhesives are pressure sensitive adhesives.

21. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

22. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

23. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 22, wherein the second film thickness is between about 0.0003 and 0.0015 inches.

24. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 23, wherein the first side of the second film is entirely coated with the second adhesive.

25. (currently amended) A transdermal-dermal, transmucosal-mucosal delivery system comprising:

a handle having a first adhesive coated on a first side thereof;

an ultra thin polymeric film with a thickness of less than 0.002 inches and having a first and a second side;

a second adhesive coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;

[[an]] a transdermally-effective active ingredient contained in an island member whose dimensions are less extensive in scope than the dimensions of said ultra thin film;

said island member comprising a backing member to which said active ingredient is secured;

said backing member being adhered to said ultra thin film layer by said ~~first~~ second adhesive layer;

a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle;

wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa.

Applicant : Gary W. Cleary et al.
Appln. No. : 10/625,327
Page -10-

26. (currently amended) The device of claim 25 in which said transdermally-effective active ingredient is incorporated into a layer of adhesive which is applied to said island backing member.

27. (currently amended) The device of claim 25 in which said transdermally-effective active ingredient is incorporated into a gel layer adhered to said island backing member.

28. (currently amended) The device of claim 27 in which said transdermally-effective active ingredient is incorporated into a layer of adhesive which is applied to said island backing member.

29. (currently amended) The device of claim 26 in which said transdermally-effective active ingredient is contained in a reservoir adhered to said island backing member.

30. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein said first side of said handle is entirely coated with the first adhesive.

31. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 30, wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

32. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 30, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

33. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein the first side of the second film is entirely coated with the second adhesive.

Applicant : Gary W. Cleary et al.
Appln. No. : 10/625,327
Page -11-

34. (original) The delivery system of claim 25 in which said release liner comprises two separate portions, a first portion covering a portion of said first side of said ultra thin film and a second portion covering the remainder of said first side of said ultra thin film;

each of said release liner portions including at least a tab portion extending beyond the perimeter of said handle, whereby a user can grasp one portion of said release liner by its said tab using one set of digits and can grasp the remainder of the delivery system using another set of digits, and then peel said first portion of said release liner away from said delivery system, and can thereafter grasp the exposed portion of the delivery system with one set of digits and grasp said tab of said second portion of said release liner with another set of digits and peel said second portion of said release liner away from the remainder of said delivery system.

35. (original) The delivery system of claim 34 in which said first portion of said release liner covers at least that portion of said handle which extends beyond said ultra thin film, such that when said first portion of said release liner is peeled away, the extending portion of said handle can be grasped, without also grasping a portion of said ultra thin film.

36. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein the first and second adhesives are pressure sensitive adhesives.

37. The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

38. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

39. (original) The transdermal-dermal, transmucosal-mucosal delivery system of claim 38, wherein the first side of the second film is entirely coated with the second adhesive.

40. (currently amended) A method of making a transdermal-dermal, transmucosal-mucosal delivery system comprising:

- providing a handle having a first adhesive coated on a first side thereof;
- providing an ultra thin polymeric film with a thickness under 0.002 inches and having a first and a second side;
- providing a second adhesive;
- coating said second adhesive to the first side of said ultra thin film;
- adhering the first adhesive of the handle to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;
- providing [[an]] a transdermally-effective active ingredient secured to said first side of said ultra thin film;
- providing a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle.